IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

BIOGEN INTERNATIONAL GMBH and BIOGEN MA INC., **Plaintiffs,** **v.** **MYLAN PHARMACEUTICALS INC.,** **Defendant.**	**Civil Action No. 1:17-cv-116-IMK**

MYLAN PHARMACEUTICALS INC.'S POST-ARGUMENT ONE-PAGE BRIEF IN RESPONSE TO THE COURT'S REQUEST

A patent's specification must "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). Expert testimony is not necessary to establish that a claim lacks written description, which can be determined "based solely on the language of the patent specification." *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927 (Fed. Cir. 2004); *Adang v. Umbeck*, No. 2007-1120, 2007 WL 3120323, at *2 (Fed. Cir. Oct. 25, 2007); *see also Idenix Pharm. LLC v. Gilead Scis., Inc.*, 941 F.3d 1149, 1163-65 (Fed. Cir. 2019) (holding claims invalid based on analyzing the specification alone); *Regents of the Univ. of Ca. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566-69 (Fed. Cir. 1997) (same). "After all, it is in the patent specification where the written description requirement must be met." *Rochester*, 358 F.3d at 927. That remains true when "the subject matter is specialized and the level of skill in the art is high" (contrary to Biogen's suggestion, ECF No. 387), as *Rochester*, *Adang*, *Idenix*, and *Regents* make clear.[1]

Nevertheless, written description is a fact question reviewed for clear error. *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 619 F.3d 1329, 1345 (Fed. Cir. 2010). In resolving that question, the Court is entitled to make findings and credibility determinations based on any evidence, including the '514 patent and the trial record. Fed. R. Civ. P. 52(a)(6); *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323-28 (Fed. Cir. 2000) (upholding written description ruling based on district court's findings as to the specification, expert testimony and admissions, and the prior art). That evidence, including Dr. Wynn's damaging admissions and Dr. Greenberg's affirmative testimony (which contrary to Biogen's suggestion accounted for the full specification and addressed therapeutic efficacy, *see* ECF No. 384 at 24-25), strongly supports Mylan's position.

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[1] *Alza v. Mylan*, 349 F. Supp. 2d 1002 (N.D.W. Va. 2004), did not state a rule *requiring* expert testimony to find a *lack* of written description. In *Alza*, the patent owner proposed expert testimony on inherent disclosure, creating a factual dispute and preventing summary judgment.

Respectfully submitted this 7th day of May, 2020.

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CERTIFICATE OF SERVICE

I hereby certify that on the 7th day of May, 2020, I electronically filed the foregoing "Mylan Pharmaceuticals Inc.'s Post-Argument One-Page Brief in Response to the Court's Request" with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following counsel of record:

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